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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/465,551	08/18/2006	Orhan K. Muratoglu	49931-0138	1443
61263	7590	03/26/2010	EXAMINER	
PROSKAUER ROSE LLP			PEPITONE, MICHAEL F	
One International Place			ART UNIT	PAPER NUMBER
Boston, MA 02110			1796	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	11/465,551	MURATOGLU ET AL.
	Examiner MICHAEL PEPITONE	Art Unit 1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 February 2009.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-4,6,10-14,16-30,32,33,35 and 42-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2-4,6,10-14,16-30,32,33,35 and 42-47 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 7/8/09
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/13/09 has been entered.

Election/Restrictions

The election by original presentation has been removed with the RCE filed 2/13/09.

Claims 2-4, 6, 10-14, 16-30, 32-33, 35, and 42-47 are pending.

Information Disclosure Statement

The information disclosure statement filed 7/8/09 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-4, 6, 10-14, 16-24, 32-33, 35, 42-43, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muratoglu *et al.* (US 2003/0149125).

Regarding claims 2 and 6: Muratoglu *et al.* teaches a process of making an irradiated crosslinked polyethylene composition (¶ 2, 37, 55), wherein the process comprises: mechanically deforming the polyethylene at a solid state {below the melt}; crystallizing the polyethylene at the deformed state; irradiating the polyethylene below the melting point of the polyethylene; and heating the irradiated polyethylene below the melting point in order to reduce the concentration of residual free radicals and to recover the original shape or preserve shape memory (¶ 37, 55).

Muratoglu *et al.* does not teach heating the irradiated polyethylene above the melting point in order to reduce the concentration of residual free radicals and to recover the original

shape or preserve shape memory. However, a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) [See MPEP 2144.05].

Regarding claims 3-4 and 10-11: Muratoglu *et al.* teaches polyethylene with substantially reduced or no detectable residual free radicals, wherein the polyethylene has a crystallinity of 51% or greater (¶ 38). Muratoglu *et al.* teaches the elastic modulus of the polyethylene is about the same or higher than that of the starting unirradiated polyethylene [instant claim 10] (¶ 30).

The Office realizes that all the claimed effects or physical properties are not positively stated by the reference. However, the reference teaches all of the claimed reagents and was prepared by a similar process. Therefore, the claimed effects and physical properties, i.e. the elastic modulus of the polyethylene is about the same or higher than that of the starting irradiated polyethylene that has been melted [instant claim 11] would inherently be achieved by a composition with all the claimed ingredients. If it is the applicants' position that this would not be the case: (1) evidence would need to be presented to support applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects with only the claimed ingredients.

Regarding claims 12-14: Muratoglu *et al.* teaches the polyethylene can be in the form of a consolidated stock, or the starting material can be also in the form of a finished product [instant claims 12-13] (¶ 12), such as medical prosthesis [instant claim 14] (¶ 76).

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Regarding claim 16: Muratoglu *et al.* teaches ultra-high molecular weight polyethylene (UHMWPE) (¶ 55, 71, 78).

Regarding claims 17-20: Muratoglu *et al.* teaches the polyethylene is in a functional relation with another piece, such as a metallic or a polymeric component, which forms an interface between the polymer and the metal or another polymeric material [instant claims 17, 19] (¶ 76); Muratoglu *et.al.* teaches metals such as stainless steel [instant claim 18] (¶ 76). Muratoglu *et al.* teaches the interface is not accessible to ethylene oxide or gas plasma during gas sterilization [instant claim 20] (¶ 76).

Regarding claims 21-24, 32, 42: Muratoglu *et al.* teaches the deformation via high frequency ultrasonic oscillation at elevated temperatures below the melting point of polyethylene {ex. 135 °C} { T_m 137 °C for UHMWPE (¶63)}, with or without the presence of a sensitizing gas (¶ 49, 67, 70).

Regarding claims 33, 35, 43, 47: Muratoglu *et al.* teaches the polyethylene is irradiated gamma radiation to a dose of greater than 20 kGy is used (¶ 44; Table 1 {100 kGy}); wherein the irradiation is carried out in air (¶ 44, 85).

Claims 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muratoglu *et al.* (US 2003/0149125) as applied to claim 2 above.

Regarding claims 25-30: Muratoglu *et al.* teaches the basic claimed process [as set forth above with respect to claim 2].

Muratoglu *et al.* does not teach a specific process which includes contacting the polyethylene with a sensitizing environment prior to irradiation [instant claim 25].

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However, Muratoglu *et al.* teaches mechanical deformation of polyethylene in the presence of a sensitizing environment {prior to irradiation} (¶ 32), wherein the sensitizing environment comprises 5% acetylene and 95% nitrogen (¶ 57, 87), or a sensitizing liquid containing octadiene with other dienes (¶ 57). At the time of invention a person of ordinary skill in the art would have found it obvious to have mechanically deformed polyethylene in the presence of a sensitizing environment {prior to irradiation} based on the invention of Muratoglu *et al.*, and would have been motivated to do so since Muratoglu *et al.* suggests that mechanical deformation of polyethylene in the presence of a sensitizing environment affords polyethylene with substantially reduced or no detectable residual free radicals (¶ 32).

Claims 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muratoglu *et al.* (US 2003/0149125) as applied to claim 6 above.

Regarding claims 44-46: Muratoglu *et al.* teaches the basic claimed process [as set forth above with respect to claim 6].

Muratoglu *et al.* does not teach a specific process which includes annealing the polyethylene with a sensitizing environment above an ambient atmospheric pressure [instant claim 44].

However, Muratoglu *et al.* teaches annealing at a temperature which is below the melting point, and elevating to a temperature that is below the melting point in the presence of a sensitizing environment (¶ 45, 65), wherein the annealing can be performed above ambient pressure, of at least about 1 atm for annealing in a sensitive environment [instant claim 44-45] (¶ 64). Muratoglu *et al.* teaches the annealing can include deformation via high frequency

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ultrasonic oscillation at elevated temperatures below the melting point of polyethylene with or without the presence of a sensitizing gas (¶ 49-50, 67, 70). At the time of invention a person of ordinary skill in the art would have found it obvious to have annealed the polyethylene in the presence of a sensitizing environment above an ambient atmospheric pressure based on the invention of Muratoglu *et al.*, and would have been motivated to do so since Muratoglu *et al.* suggests that annealing with mechanical deformation in the presence of a sensitizing environment affords polyethylene with substantially reduced or no detectable residual free radicals (¶ 45, 50).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26, and 46-47 of U.S. Patent No. 6,852,772. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because the claimed process steps of making an irradiated crosslinked polyethylene via irradiating polyethylene below the melt, mechanically deforming, annealing, and crystallizing substantially overlap in scope.

US '772 does not claim the process steps in the same order as the instant application. However, a *prima facie case of obviousness exists where changes in the sequence of adding ingredients derived from the prior art process steps.* *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie obvious* in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie obvious*.) [See MPEP 2144.04].

US '772 does not claim heating the irradiated polyethylene above the melting point in order to reduce the concentration of residual free radicals and to recover the original shape or preserve shape memory. However, a *prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties.* *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) [See MPEP 2144.05].

Response to Arguments

Applicant's arguments filed 2/13/09 have been fully considered but they are not persuasive. The rejection of claims 2-4, 6, 10-14, 16-30, 32-33, 35, and 42-47 based upon Muratoglu *et al.* (US 2003/0149125) is maintained for reason of record and following response.

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Muratoglu *et al.* (US '125) discloses a process of making an irradiated crosslinked polyethylene composition (¶ 2, 37, 55), wherein the process comprises: mechanically deforming the polyethylene at a solid state {below the melt}; crystallizing the polyethylene at the deformed state; irradiating the polyethylene below the melting point of the polyethylene; and heating the irradiated polyethylene below the melting point in order to reduce the concentration of residual free radicals and to recover the original shape or preserve shape memory (¶ 37, 55) {see claim 2 above}.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL PEPITONE whose telephone number is (571)270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo/
Supervisory Patent Examiner, Art Unit 1796

MFP
1-March-10

Receipt date: 07/08/2009

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***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.P./